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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,135

06/08/2006

Dan Hashimshony

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05/05/2009

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EXAMINER

DANEGA, RENEE A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,135	Applicant(s) HASHIMSHONY ET AL.	
	Examiner Renee Danega	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-8, 15-16, 18-19, 23-27, 29-32, 39-40, 42-43, and 47-48, 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagle (US 6225107).

- Regarding claims 1 and 24, Nagle teaches a device and method of providing a device comprising a structure for receiving and holding a tissue specimen (10), device positional references associated with the structure for fixing the orientation of the tissue specimen when held by the device (30) and positioning the tissue specimen within the device so as to reflect the tissue specimen positional references (30) and wherein the structure comprises a first outline frame (10), designed to receive and hold a tissue specimen therebetween; and at least one holder (40) (420 (45) for holding the first frame with the specimen thus fixing the tissue orientation (Figure 1) (abstract) (column 4, lines 5-16, 54-65).
- Regarding claims 2 and 26, Nagle teaches the device configured to define tissue lateral and superior sides and a top surface (column 4, lines 1-18).
- Regarding claims 3 and 27, Nagle teaches the device is substantially transparent to at least one imaging modality selected from the group

consisting of x-ray, gamma, and MRI (column 3, lines 9-10) (column 4, line 66 - column 5, line 2)

- Regarding claims 5 and 29, Nagle teaches the device positional references (30) are built into the structure (10) (Figure 1).
- Regarding claims 6 and 30, Nagle teaches the device positional references based on a color code (column 3, lines 10-17) (column 5, lines 35-40).
- Regarding claims 7 and 31, Nagle teaches the device positional references based on sutures of different lengths (column 4, lines 5-27).
- Regarding claims 8 and 32, Nagle teaches the device formed as a rigid body (column 3, lines 10-15).
- Regarding claims 15 and 39, Nagle teaches the device formed as a box outline comprising a box outline body, lid, and at least one holder (column 2, lines 55-67).
- Regarding claims 16 and 40, Nagle teaches the structure comprising first (22) and second (24) frames designed to be superimposed and receive and hold the tissue (12) there between and at least one holder (40) for holding first and second frames together thus fixing the orientation of the specimen (column 2, lines 55-67) (Figure 1).
- Regarding claims 18, 42, 47, and 50, Nagle teaches the device further including a lining (24) (Figure 1).

- Regarding claims 19, 43, 48, and 51, Nagle teaches the device further including a grid (column 4, lines 44-53).
- Regarding claim 23, Nagle teaches the device provided in a plurality of sizes (column 2 line 67-column 3, line 2).
- Regarding claim 25, Nagle teaches maintaining the specimen immobile in the device (column 4, lines 37-49).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claims 1 and 24 above, and further in view of Russell (US 5383234).

- Regarding claims 9 and 33, Nagle doesn't teach the device to be formed as a flexible body. However, Russell teaches a device for tissue handling in which the container is formed from flexible material to permit manipulation by a radiologist without exposure to fluids (column 2, lines 62-66). It would have been obvious in view of Russell to make the device out of flexible material in order to permit tissue manipulation without direct contact.

5. Claims 4, 10, 12, 13, 28, 34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claims 1 and 24 above, and further in view of Heaven et al. (US 5524633) .

- Regarding claims 4 and 28, Nagle doesn't teach the device configured to receive tissue prior to its complete removal. However, Heaven teaches a tissue handling device for in vivo manipulation isolation and removal of tissue (column 1, lines 19-28) (abstract). It would have been obvious in view of Heaven to provide for Nagle's device to be able to receive tissue prior to complete removal in order to prevent disease spreading during the removal for examination.
- Regarding claims 10, 12, 34, and 36, Nagle doesn't teach the device being a stretchable body or sac-like mesh. However, Heaven teaches a device for tissue handling with a stretchable body and sac-like mesh layer for excising tissue from within the body (abstract). It would have been obvious in view of Heaven to provide stretchable or sac-like mesh in the device in order to manipulate it in the body for tissue collection in vivo.
- Regarding claims 13 and 37, Nagle doesn't teach the device to be a stretchable stocking. However, Heaven teaches a device for tissue handling with a stretchable body and stocking configuration for in vivo tissue handling (Figure 12) (abstract). It would have been obvious in view of Heaven to provide a stocking configuration for in vivo manipulation of tissue.

6. Claims 11, 14, 35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claims 1 and 24 above, and further in view of Glassman (US 5105457).

- Regarding claims 11, 14, 35, and 38, Nagle doesn't teach the device to form an expansible body or resilient cage. However, Glassman teaches a tissue handling device that is an expansible cage with expanding sides (17) (14) (Figure 1). It would have been obvious in view of Glassman to provide an expansible cage in order to hold tissues of various sizes in place.

7. Claims 17, 41, 46, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claims 15, 16, 24, and 40 above, and further in view of Douglas (US 3743084).

- Regarding claims 17, 41, 46, and 49, Nagle teaches the holder to be a hinge but not a surgical latex band. However, Douglas teaches a package held together with a spring or a rubber band to be an obvious substitution (column 1, lines 64-68). It would have been obvious in view of Douglas to provide a holder to be a latex band in Nagle's device.

8. Claims 20, 21, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claims 1 and 24 above.

- Regarding claims 20, 21, 44, and 45 Nagle teaches applying a force (column 4 lines 37-49) but doesn't specifically teach the force to be less than 500 grams and between 20 and 200 grams. It would have been

obvious to one having ordinary skill in the art at the time the invention was made to apply a force of 20-200 grams to conform the tissue to the reference device, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claim 1 above, and further in view of Garrigus (US 4837795).

- Regarding claim 22, Nagle doesn't teach handles on the device. However, Garrigus teaches a tissue handling device with handles (31) (Figure 1). It would have been obvious in view of Garrigus to provide handles on the device in order more easily move and grab the device.

Response to Arguments

10. Applicant's arguments filed 17 February 2009 have been fully considered but they are not persuasive. Examiner respectfully disagrees with applicant's assertion that the device of Nagle doesn't comprise outline frames. The Nagle carrier is made of an outline body forming a box shape. Examiner points out that all boxes comprise an outline frame and further are outline frames since they are empty in the interior to carry or retain objects. An outline can have sides or walls and since applicant uses the word "comprising", the claim doesn't exclude any outline body having walls.

11. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

(i.e., being able to see the tissue through the outline frames) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736